

## All-In-One Universal Cartridge Based Truly Modular Electrolyte Analyzer

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**Abstract :** Measurement of routine clinical electrolyte tests is common in labs worldwide for screening of illness or diseases. All the analyzers for the measurement of electrolyte parameters have sensors, reagents, sampler, pump tubing, valve, other tubing's separate that are either expensive, require heavy maintenance and have a short shelf-life. Moreover, the costs required to maintain such Lab instrumentation is high and this limits the use of the device to only highly specialized personnel and sophisticated labs. In order to provide Healthcare Diagnostics to ALL at affordable costs, there is a need for an All-in-one Universal Modular Cartridge that contains sensors, reagents, sampler, valve, pump tubing, and other tubing's in one single integrated module-in-module cartridge that is affordable, reliable, easy-to-use, requires very low sample volume and is truly modular and maintenance-free. DiaSys India has developed a World's first, Patent Pending, Versatile All-in-one Universal Module-in-Module Cartridge based Electrolyte Analyzer (QDx InstaLyte) that can perform sodium, potassium, chloride, calcium, pH, lithium tests. QDx InstaLyte incorporates High Performance, Inexpensive All-in-one Universal Cartridge for rapid quantitative measurement of electrolytes in body fluids. Our proposed methodology utilizes Advanced & Improved long life ISE sensors to provide a sensitive and accurate result in 120 sec with just 100  $\mu$ l of sample volume. The All-in-One Universal Cartridge has a very low reagent consumption capable of maximum of 1000 tests with a Use-life of 3-4 months and a long Shelf life of 12-18 months at 4-25°C making it very cost-effective. Methods: QDx InstaLyte analyzers with All-in-one Universal Modular Cartridges were independently evaluated with three R&D lots for Method Performance (Linearity, Precision, Method Comparison, Cartridge Stability) to measure Sodium, Potassium, Chloride. Method Comparison was done against Medica EasyLyte Plus Na/K/Cl Electrolyte Analyzer, a mid-size lab based clinical chemistry analyzer with N = 100 samples run over 10 days. Within-run precision study was done using modified CLSI guidelines with N = 20 samples and day-to-day precision study was done for 7 consecutive days using Trulab N & P Quality Control Samples. Accelerated stability testing was done at 45°C for 4 weeks with Production Lots. Results: Data analysis indicates that the CV for within-run precision for Na is  $\leq 1\%$ , for K is  $\leq 2\%$ , and for Cl is  $\leq 2\%$  and with  $R^2 \geq 0.95$  for Method Comparison. Further, the All-in-One Universal Cartridge is stable up to 12-18 months at 4-25°C storage temperature based on preliminary extrapolated data. Conclusion: The Developed Technology Platform of All-in-One Universal Module-in-Module Cartridge based QDx InstaLyte is Reliable and meets all the performance specifications of the lab and is Truly Modular and Maintenance-Free. Hence, it can be easily adapted for low cost, sensitive and rapid measurement of electrolyte tests in low resource settings such as in urban, semi-urban and rural areas in the developing countries and can be used as a Point-of-care testing system for worldwide applications.

**Keywords :** all-in-one modular cartridge, electrolytes, maintenance free, QDx instalyte

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